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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,446	02/09/2004	George Inana	GMR-0001	4156

7590 05/16/2006

Margaret J. McLaren, Ph.D., Esq.
6500 SW 133rd Drive
Miami, FL 33156

EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,446	INANA ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39,53,57,58 and 60* is/are pending in the application.

4a) Of the above claim(s) *14 and 18-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-17,53,57,58 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 2/21/06, are acknowledged.

Claims 1 and 58 have been amended.
Claims 54-56, 59, and 61-62 have been cancelled.
Claims 1-39, 53, 57-58, and 60 are pending.

2. Claims 14 and 18-39 as well as SEQ ID Nos: 1-14 and 16-17 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-13, 15-17, 53, 57-58, and 60 are being acted upon.

3. Applicants submission of the date from reference S is acknowledged. However, the information must be included on the information disclosure itself in order for the examiner to consider the reference.

4. The rejection of the claims 1-12, 53, 57-58, and 60 under 35 U.S.C 112 second paragraph is withdrawn in view of Applicant's amendment which replaces the term "modulates" with the term "decreases". Additionally, the rejection of claims 1-13, 15-17, 53, 57-58, and 60 under 35 U.S.C 112 first paragraph, as outlined in section A) of the office action mailed 10/21/05, is withdrawn in view of Applicant's amendment. Specifically, applicant has removed the phrase "extracellular matrix of a retina or choroids" from claim 1. Additionally, the cancellation of claims 54-56, 59, and 61-62 renders the rejection of the claims moot.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 15-17, 53, 57-58, and 60 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth previously, Claims 1-13, 15-17, and 53-62 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A method comprising contacting an extracellular matrix of a retina or choroid" (Claim 1, and dependant claims 2-13, 15-17 and 53-62).

B) A method for delaying a disease comprising contacting a cell with an agent that modulates the expression of a gene "or product thereof" (Claim 1 and 2 and dependant claims 3-13, 15-17 and 53-62).

C) The method where the extracellular matrix is in the retina, choroid, or vitreous (Claims 54-56).

D) The method wherein the antibody is administered by intraocular injection, to the retina, subretinal space, choroid, or vitreous (Claims 58-62).

In the Preliminary Amendments, filed 8/11/05 and 8/19/05, Applicant indicates that support for the new limitations of Claim 1 can be found at pages 8 and 31 of the specification.

A review of the specification fails to reveal support for the new limitations.

Regarding A), at page 8, the specification discloses, "the AMDP-related or phagocytosis related gene…may be located within the cell or in an extracellular matrix." Note that the specification does not disclose contacting an extracellular matrix with an agent, merely that the AMDP related gene to be modulated may be in the extracellular matrix.

Regarding B), at page 31, the specification discloses, "Preferred genes/proteins to be targeted..", however, it does not specifically state modulating genes or products thereof. While a protein may be inferred to be a product of a gene, this specific example is insufficient to support the claims that recite the broad statement of a gene "or product thereof."

Regarding C), the specification as filed does not provide a written description for the limitation of claims 54-56, where the extracellular matrix is in the retina, choroid, or vitreous.

Regarding D), at pg. 53, the specification discloses delivery of a vector by intraocular injection. However, the disclosure does not recite administering an antibody. It is noted that all cites relating to administration of an antibody are found in specific examples and not in generic disclosures. Thus, Applicant has improperly attempted to claim specific limitations set forth only in specific examples of the more generic claims of the instant application.

With regard to the rejection of claims 1-13, 15-17, 53, 57-58, and 60 as outlined in sections B) above, and claims 58 and 60 as outlined in section D) above, Applicant's arguments, filed 2/21/06, have been fully considered, but they are not persuasive.

With regard to B), Applicant argues the specification on pg. 31 teaches "preferred genes/proteins to be targeted", and thus provides support for a method of delaying or reversing retinal disease with an agent that decreases the expression or activity of an AMDP-related protein. However, while the instant specification discloses on pg. 31 that agents can modulate or down-regulate (i.e. decrease) the expression of mRNA or protein of an AMDP-related gene, there does not appear to be a disclosure of delaying disease with an agent that down-regulates or decreases the "activity of an AMDP-related protein", as now claimed.

With regard to D), Applicant argues that the amendment to claim 58 to recite "by injection to the eye" obviates the rejection of the claim. Applicant cites that support for the amendment can be found on pg. 69 of the specification. However, a review of pg. 69 reveals a disclosure of a specific example involving injection of an MT1-MMP antibody into the eye of an RCS rat. This cannot be considered adequate written description for the generic method of the claims, which has a much broader scope than this specific example, since it is drawn to delaying or reversing a retinal or choroidal degenerative disease or condition in **any** subject. Likewise, Applicant argues that support for claim 60 can be found in the same specific example since the specification states that the specific examples should not be construed as limiting the scope or content of the invention. While specific examples may not be "limiting the scope of content of the invention", they cannot be cited in support of that which they do not disclose. The fact remains that Applicant has not disclosed a method of delaying retinal disease in a subject, as broadly claimed, by administering an MT1-MMP specific antibody into the eye or to the subretinal space. Applicant has only disclosed injecting an MT1-MMP antibody subretinally into the eyes of an RCS rat.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 15-17, 53, 57-58, and 60 stand rejected under 35 U.S.C. 102(b) as being anticipated by US Patent application

publication 2003/0199440 as evidenced by US Patent application publication 2005/0059595.

As set forth previously, The '440 patent application teaches a method for the treatment of damaged tissues associated with age-related macular degeneration (AMD) by administering an inhibitor of adverse proteases (see paragraphs 216-218, and claim 11). Treatment is defined, in one embodiment, as being curative (see paragraph 75), and hence this method will reverse and delay AMD. The specification of the '440 patent application further discloses that said inhibitor can be specific for MMP14 (see paragraph 222), which shares 99.9% sequence identity with the MT1-MMP of the instant application. Furthermore, said inhibitor can be an antibody (paragraph 309). Claim 6 is included since the '440 patent application teaches that "treatment" includes prophylactic treatment (see paragraph 75). Claim 13 and 16 are included since the '440 patent application teaches that the treatment inhibits the specific proteolytic degradation effects of MMP14 (paragraph 68), i.e. downregulates/ neutralizes its activity. Furthermore, claims 17 is included since '440 further teaches that matrix metalloproteinases are endopeptidases that degrade the extracellular matrix. Therefore, inhibition of the proteolytic degradation effects of MMP14 would inherently lead to loss of extracellular matrix degradation activity. Claim 57 is included since '440 teaches that an antibody can be monoclonal (paragraph 499). Claim 58 is included since '440 teaches that the inhibitor (i.e. antibody) can be given by intraocular administration (see paragraph 63). Claims 9, 12 and 54-62 are included since US Patent application publication '595 teaches that intraocular injection can allow diffusion throughout the vitreous, the entire retina, and the choroid. Thus, administration via an intraocular route would also have inherently administered the antibody to the retina (including the subretinal space, an RPE cell, and the interphotoreceptor matrix or intracellular matrix of said retina), the choroid (including the extracellular matrix of the choroid), and the vitreous (including the extracellular matrix of the vitreous). Claims 10-11 are included since the location of MT1-MMP is inherent to AMD (see pg. 62 of the instant specification) Therefore, since the '440 application involves treating AMD, the MT1-MMP (MMP14) would have inherently been located in the RPE cell and extracellular matrix.

Applicant's arguments filed 2/21/06 have been fully considered but they are not persuasive with regard to claims 1-13, 15-17, 53, 57-58, and 60.

Applicant argues that the '440 application does not anticipate the instant invention because it does not teach or suggest using an agent that decreases the expression or activity of an AMD-related gene. However, as outlined in the original rejection, the '440 application teaches a method of treating AMD by administering an antibody specific for MT1-MMP, and that said treatment inhibits the specific proteolytic degradation effects of MMP14 (i.e. an activity of MMP14). Since MMP14 is an AMD-related gene (i.e. MMP14 is a species within the genus of AMD related genes), the reference does anticipate the instant invention. It is well established that a teaching of a species anticipates the genus.

Applicant further argues that the '440 application is not an enabling reference, particularly in view of the example

provided in paragraphs 641-665 which demonstrates a deleterious effect on wound healing when a non-specific protease inhibitor, was administered, and no effect on wound healing using a MMP-3 inhibitor. This is not sufficient evidence that the '440 application is not enabling for administering an **MMP14 specific antibody** to treat **AMD**. Thus, Applicant has not provided any evidence, but merely asserted, that the '440 application is not enabling. As acknowledged by Applicant, the '440 application teaches treating damaged tissue, including those associated with AMD, by administering an inhibitor (including an antibody) specific for MMP14. Absent evidence to the contrary, the '440 application is considered to be an enabled reference.

7. No claim is allowed.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

90. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600
April 27, 2006

5/7/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER